APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,429	01/22/2001	Georg Casari	109904-09012	9477

	EXAMINER
7590 07/16/2004	ROSALES HANNER, MORELLA I

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ART UNIT	PAPER NUMBER
2128	

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-22-2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 26* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 26* is/are rejected.

7)☐ Claim(s) *1-3 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *22 January 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date *06/4/2001*.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____ .

Detailed Action

1.　　**Claims 1 – 26** have been examined and are pending.

Priority

2.　　The Office acknowledges Applicant's claim for domestic priority under 35 U.S.C. 119(e) for application **60/177223** filed on **01/21/2000**.

Drawings

3.　　Figures 1 and 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

4.　　The information disclosure statements (IDS) submitted on May 7th 2001 and June 4th 2001 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Objections

5.　　**Claim 2** is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

dependent form, or rewrite the claim(s) in independent form. It is unclear how this claim

further limits the method of claim 1.

6.   **Claim 8** is objected to because of the following informalities: it appears that line

4 of the claim should recite "Eigen values/eigen vectors" instead of

"Eighenvalues/eigenvectors" . Appropriate correction is required.

7.   **Claims 1 and 3** are objected to because of the following informalities: it appears

that claim 1 is missing a period "." and claim 3 is missing a semicolon ";" at the end of

lines 5 - 9 . Appropriate correction is required.

Claim Rejections – 35 USC § 112

8.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
>
> claiming the subject matter which the applicant regards as his invention.

8.1   **Claim 5** recites the limitation "descriptive variables" in line 2. There is insufficient

antecedent basis for this limitation in the claim.

8.2   **Claim 7** recites the limitation "similarity matrix" in line 2. There is insufficient

antecedent basis for this limitation in the claim. Also the claim recites "whereby Step b)

can comprise **one or more of the methods in claim 4**" Claim 4 recites only one

method. Appropriate correction is required.

8.3   **Claim 2** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite

in that it fails to point out what is included or excluded by the claim language. This claim

is an omnibus type claim.

8.4   **Claims 17 and 21** are rejected under 35 U.S.C. 112, second paragraph, as

being incomplete for omitting essential steps, such omission amounting to a gap

between the steps. See MPEP § 2172.01. The omitted step is the definition of the

metabolic path which is essential for its proper observation.

Claim Interpretation

9.   In the interest of compact persecution the following claims have been examined

as follows:

- **Claim 2** has been interpreted as a being drawn to the method according to claim

   1 where the analysis of large and/or complex biological data sets from arrayed

   bio molecules or derivative/substitutes experiments.

- Line 7 of **claim 3** corresponds to the method of Exclusion of outliers.

- Line 2 of **claim 7** corresponds to a similarity table instead of a similarity matrix.

Claim Rejections - 35 USC § 102

10.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public

use or on sale in this country, more than one year prior to the date of application for patent in the United

States.

10.1   **Claims 1 – 26** are rejected under 35 U.S.C. 102(b) as being clearly

anticipated by a printed publication by Michael B. Eisen, Paul T. Spellman, Patrick O.

Brown[t], and David Botstein; titled "Cluster analysis and display of genome-wide

expression patterns", hereafter referred to as *Eisen*.

10.1.1   As regard to **Claims 1, 2 and 17**, *Eisen* teaches [Pg 14864, Materials and

Methods] an analysis method for large and/or complex biological data sets from

molecular biology experiments, arrayed bio molecules or derivatives/substitutes,

comprising:

> a)   importing data in a table data structure;
>
> b)   comparing data points;
>
> c)   calculating an optimized data representation; and
>
> c)   displaying the representation.

10.1.2   As regard to **Claim 3**, *Eisen* teaches [Pg 14863, right col., last paragraph]

modifying the original measurements to account for the experimental design and/or to

emphasize aspects in the following analysis steps by using one of or combinations of

methods listed below:

> Shifting of values,

Scaling of values,

Exclusion of outliers,

Merging of multiple measurements,

Correction of neighbor influences, or

Selection of characteristics subsets.

10.1.2 As regard to **Claim 4**, *Eisen* teaches [**Pg 14863, left col., 3rd full paragraph**] comparing data points by statistical organization of complex gene expression data on a generalized similarity table for the data points and the derived vectors of the similarity table define the optimized representation. Eigen values

10.1.3 As regard to **Claims 5 and 6**, *Eisen* teaches [**Pg 14863, right col., last two sentences**] comparing data points on a generalized similarity table to derive the representation of the data points.

10.1.4 As regard to **Claims 7, 8, 12 and 13**, *Eisen* teaches [**Pg 14864, left col., Materials and Methods**] using a similarity table of smaller dimensions and the representation of the data points may be calculated by using deriving eigen values and eigen vectors from the similarity table and constructing eigen vectors and the representation of data points as linear combinations of the original data.

10.1.5 As regard to **Claim 9**, *Eisen* teaches [**Pg 14864, right Col., Display**] graphical visualization of the optimized data representation and indication of the nature of the computed relationships;

10.1.6 As regard to **Claim 10**, *Eisen* teaches [**Pg 14864, right Col., Results**] graphical visualization of the optimized data representation is performed by placing data points at the coordinates obtained in the eigenvectors.

10.1.7 As regard to **Claim 11**, *Eisen* teaches [**Pg 14864, right Col., Results**] that the optimal subset of eigen vectors is chosen for maximal explanation of the variance in the data as indicated by the biggest corresponding eigen values.

10.1.8 As regard to **Claim 14**, *Eisen* teaches [**Pg 14864, Materials and Methods**] external biological or chemical or medical information that is imported into the representation according to co-ordinates as calculated by a projection onto the eigen vectors and where their co-ordinates may be scaled independently.

10.1.9 As regard to **Claims 15 and 16**, *Eisen* teaches [**Pg 14867, Discussion**] a method, performed on a computer, for the analysis of large and/or complex biological data sets by extracting inherent structures of optimized explanatory power.

10.1.10   As regard to **Claims 18 and 19**, *Eisen* teaches [Pg 14864, Materials and

Methods] an analysis method for large and/or complex biological data sets from

molecular biology experiments, the method comprising:

  a)   importing data obtained from the experiments;

  b)   calculating a data representation using an algorithm;

  c)   displaying the data representation;

  d)   selecting a data point of interest;

  e)   displaying the selected data point so that the selected data point

          can be distinguished from non-selected data points; **and**

  f)   displaying data points representing the selected gene so that the

          data points are displayed as selected data points.

10.1.11   As regard to **Claim 20**, *Eisen* teaches [Pg 14864, Materials and Methods & Pg

14867, Discussion] an analysis method for large and/or complex biological data sets from

molecular biology experiments, the method comprising:

  a)   importing data obtained from the experiments;

  b)   calculating a data representation using an algorithm;

  c)   displaying the data representation;

  d)   selecting a data point of interest; and

e)   using a data base search to obtain additional information

regarding the compound, gene, cell, virus, sequence, or

substance represented by the selected data point.

10.1.12   As regard to **Claims 21 and 22**, *Eisen* teaches [**Pg 14864, Materials and**

Methods & Pg 14867, Discussion] a computer implemented method for analysis of large and/or complex

biological data sets from molecular biology experiments, the method comprising:

a)   importing data obtained from the experiments into a computer data storage

system;

b)   calculating a data representation of at least a portion of the imported data

using a computer implemented algorithm; and

c)   displaying the representation on a computer display.

10.1.13   As regard to **Claim 23**, *Eisen* teaches [**Pg 14864, Materials and Methods & Pg**

14867, Discussion] a computer implemented method for analysis of large and/or complex biological

data sets from molecular biology experiments, the method comprising:

a)   importing data obtained from the experiments into a computer data storage

system;

b)   calculating a data representation using a computer implemented algorithm;

c)   displaying the data representation on a computer display;

d)   selecting a data point of interest from the displayed data; and

e)   displaying the selected data point so that the selected data point can be distinguished from non-selected data points on the computer display.

10.1.14   As regard to **Claim 24**, *Eisen* teaches [Pg 14864, Materials and Methods & Pg 14867, Discussion] a computer readable medium having computer readable program code for analysis of large and / or complex biological data sets from molecular biology experiments, the computer readable medium and a computer input/output system being capable of working together to cant' out the steps of:

a)   importing data obtained from the experiments into a computer data storage system;

b)   calculating a data representation using a computer implemented algorithm;

c)   displaying the data representation on a computer display;

d)   selecting a data point of interest from the displayed data; and

e)   displaying the selected data point so that the selected data point can be distinguished from non-selected data points on the computer display.

10.1.15   As regard to **Claim 25**, *Eisen* teaches [Pg 14864, Materials and Methods & Pg 14867, Discussion] a computer-implemented method for analysis of large and/or complex biological data sets from molecular biology experiments, the method comprising:

a) importing data obtained from the experiments into a computer data storage system;

b) calculating a data representation using a computer implemented algorithm;

c) displaying the data representation on a computer display;

d) selecting a data point of interest from the displayed data; and

e) using a computer data base search engine to obtain additional information regarding the compound, gene, cell, virus, sequence, or substance represented by the selected data point.

10.1.16 As regard to **Claim 26**, *Eisen* teaches [**Pg 14864, Materials and Methods & Pg 14867, Discussion**] a computer readable medium having computer readable program code for analysis of large and/or complex biological data sets from molecular biology experiments, the computer readable medium and a computer input/output system being capable of working together to carry out the steps of:

a) importing data obtained from the experiments into a computer data storage system;

b) calculating a data representation using a computer implemented algorithm;

     c)   displaying the data representation on a computer display;

     d)   selecting a data point of interest from the displayed data; and

     e)   using a computer data base search engine to obtain additional

            information regarding the compound, gene, cell, virus, sequence,

            or substance represented by the selected data point.

Additional references

11. The following is a list of references that are relevant to the claimed invention but were not cited by the examiner:

- "Data Note System for Capturing Laboratory Data" by Mark Graves, Genomics 43, 232-236 (1997).
- U.S. Patent No. 6,468,476 issued to Friend et al.

Additional Information

12. Applicant is requested to supply information related to **the bioSCOUT system** such as user manual, design and specification description as of the time of the filing of the instant application.

13. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Morella Rosales-Hanner whose telephone number is (703) 305-8883. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Kevin Teska can be reached on 703 305-9704. The fax number for the

organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is (703) 305-

3900.

MRH

July 08th, 2004

KEVIN J. TESKA
SUPERVISORY
PATENT EXAMINER